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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/394,006	09/10/1999	DOLORES M. BERGER	P-4762	3611

7590 05/30/2003

RICHARD J RODRICK ESQ
BECTON DICKINSON AND COMPANY
1 BECTON DRIVE
FRANKLIN LAKES, NJ 07417

EXAMINER

FORMAN, BETTY J

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 05/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/394,006	BERGER ET AL.	
	Examiner	Art Unit	
	BJ Forman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,6-8,10 and 12-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,6-8,10 and 12-17 is/are rejected.
- 7) ☒ Claim(s) 1,7 and 8 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 14 March 2003 has been entered.

2. This action is in response to papers filed 14 March 2003 in which claims 1, 7, 8, 10 and 12 were amended. All of the amendments have been thoroughly reviewed and entered. The previous rejections in the Office Action dated 11 April 2002 are withdrawn in view of the amendments.

All of the arguments have been thoroughly reviewed but are deemed moot in view of the amendments, withdrawn rejections and new grounds for rejection. New grounds for rejection are discussed.

Claims 1-4, 6-8, 10 and 12-17 are under prosecution.

Claim Objections

3. Claims 1, 7 and 8 are objected to because of the following typographical errors:
- a. Claim 1, step (a), line 3, "less" is misspelled "les".

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- b. Claim 1, step (b), lines 4 and 6, "substance" is misspelled "substances".
- c. Claim 7, line 2, "substance" is misspelled "substances".
- d. Claim 8, line 2, "substance" is misspelled "substances".

Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1, 2, 4, 12-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Baltzer et al (Acta Chemica Scandinavica, 1982, 36: 31-38).

The claims are drawn to a composition comprising:

- (a) a first substance capable of precipitating or denaturing proteins, comprising at least one alcohol or ketone whose concentration is less than 80% of the total composition; and
 - (b) dimethyl sulfoxide whose concentration is greater than 20% of the total composition,
- wherein the concentrations of said first substances and dimethyl sulfoxide are

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effective to stabilize the nucleic acids of said at least one cell in a specimen at ambient temperature, and further wherein the combined concentration of said first substances and dimethyl sulfoxide is 100% of said composition.

Regarding Claim 1, 2, 4 and 12-17, Baltzer et al disclose a composition comprising less than 80% methanol and greater than 20% DMSO (Abstract, third paragraph and Tables 1-2).

The intended use and functional language recited in the preamble of the claim i.e. "for stabilizing nucleic acids of at least one cell in a specimen at ambient temperature"; "capable of precipitating or denaturing proteins"; "effective to stabilize the nucleic acids of said at least one cell in a specimen at ambient temperature"; "wherein said nucleic acid is DNA (RNA, ribosomal RNA)"; and "wherein said cell is a prokaryote or eukaryote (microorganism) is not given patentable weight because the courts have stated that a composition cannot have mutually exclusive properties.

"Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990) see MPEP § 2112.01.

As such, the composition of Baltzer comprising less than 80% alcohol and greater than 20% DMSO is encompassed by the instantly claimed composition.

Claim Rejections - 35 USC § 102/103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1, 2, 4, 13-17 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Rogers (U.S. Patent No. 6,232,092 B1, filed 2 October 1998).

Rogers discloses a composition for stabilizing the nucleic acids of at least one cell in a sample comprising; at least one alcohol having a concentration of 80% and DMSO having a concentration of 20%, wherein the first substance is a methanol, wherein the nucleic acids are RNA or DNA and wherein the cell is eukaryotic (Column 4, lines 12-15 and Column 5, line 50-Column 6, line 3).

The preceding rejection is based on judicial precedent following *In re Fitzgerald*, 205 USPQ 594 because Rogers is silent with regard to the alcohol being greater than 80% and the DMSO being less than 20%. However, the greater than 80% and less than 20% recited in Claim 1 is deemed to be inherent in the composition of Rogers because the claims encompass alcohol at 80.00000000.....1% and DMSO at 19.999999999999999...9%. The composition of Rogers would inherently fall within the limitations of the claims because any compositions measured and mixed in a laboratory would differ due to a margin of error in measurement and/or evaporation and/or spillage. Therefore, the compositions prepared using the method of Rogers would inherently produce a composition comprising first and second substances having concentrations of less than 80% and greater than 20 % respectively.

Alternatively, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to adjust the composition concentrations of Rogers using

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routine experimentation to thereby derive an optimal composition for stabilizing cellular nucleic acids because the skilled practitioner in the art would have been motivated to optimize the composition to thereby maximize stabilization. It is noted that *In re Aller*, 220 F.2d 454,456, 105 USPQ 233,235 states where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum by routine experimentation.

Furthermore, the functional language and intended use for the composition recited in the claims are not given patentable weight because the courts have stated that a composition cannot have mutually exclusive properties.

Therefore, the composition of Rogers inherently stabilizes nucleic acids of at least one cell in a specimen at ambient temperature, is capable of precipitating or denaturing proteins, wherein said nucleic acid is DNA (RNA, ribosomal RNA) and wherein said cell is a prokaryote or eukaryote (microorganism).

The burden is on applicant to show that the claimed concentrations of less than 80% DMSO and greater than 20 % alcohol is either different or non-obvious over that of Rogers.

Conclusion

8. Claims 6, 7, 8, 10 and 12 are free of the prior art and may be placed in condition for allowance following resolution of the above rejections.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:30 TO 4:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



BJ Forman, Ph.D.
Patent Examiner
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May 29, 2003